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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,103	10/14/2005	Andrei Bugrim	GENE.003.PCT	5310

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EXAMINER	
SKOWRONEK, KARLHEINZ R	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,103	BUGRIM ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-14-2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable

petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Status

Claims 1-3 are pending.

Claims 1-3 are being examined.

Specification

The disclosure is objected to because of the following informalities:

Page 4, paragraph 8, line 5 of the specification makes reference to another US application however the application number is missing.

Page 9, paragraph 2, line 5 of the specification makes reference to another US application however the application number is missing.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see p. 1, paragraph 2, line 4 and 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities:

Claim 1 step (d) recites the "obtain" in line 2 and should recite "obtained";

Claim 3 contains 2 periods, a first period after the step d and second period after step e. Each claim is to begin with a capital letter and end with a period. (MPEP 608.01(m)).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is unclear because claim 2 is dependent from itself. For the purpose of examination claim 2 will be interpreted ass depending from claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al. (Genome scale gene expression analysis and pathway reconstruction in KEGG, Genome Informatics, 10:94-103, 1999).

The claim is directed to a method for reconstruction the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows that the data is linked to metabolic pathways and inter connections are identified to create a map the organism's metabolism (figure 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. (Genome scale gene expression analysis and pathway reconstruction in KEGG, Genome Informatics, 10:94-103, 1999) in view of Okubo et al. (Nature Genetics, Vol. 2, p173-179, November 1992).

The claim is directed to a method for reconstruction the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created. In an embodiment, the data is Expressed sequence tag (EST) data.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows that the data is linked to metabolic pathways and inter connections are identified to create a map the organism's metabolism (figure 4).

Nakao et al does not show EST data.

Okubo et al shows expression data that comprises EST data can be used in mapping (p. 178, col. 1). Okubo shows the advantage of using expressed sequence tags results from a comparison of data from the same cells under different physiological conditions that will aid in the understanding of cell- and time-dependent control of gene gene expression (p. 176-177, col. 2). Okubo et al shows that map of expressed gene will help in the search for biologically and industrially interesting genes (p. 173, col. 1).

It would have been obvious to one of skill in the art to modify the method of metabolism reconstruction of Nakao et al by the incorporation of EST data of Okubo et

al because Okubo et al shows that a map of expressed genes will facilitate the search for biologically and industrially interesting genes.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. (Genomescale gene expression analysis and pathway reconstruction in KEGG, Genome Informatics, 10:94-103, 1999) in view of Karp et al. (Trends in biotechnology, Vol. 17, p. 275-281, 1999).

The claim is directed to a method for reconstruction the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows that the data is linked to metabolic pathways and inter connections are identified to create a map the organism's metabolism (figure 4). Nakao et al. shows that the metabolic reconstruction also comprises data regarding metabolism of an organism for both a reference (non-diseased) and perturbed (diseased) state (p. 95)

Nakao et al. does not show the identification of drug targets.

Karp et al. shows that drug targets can be identified through the analysis of pathway genome databases (p. 278, col. 2 to p. 279, col. 1). Karp et al. shows (abstract).

I t would have been obvious to one of skill in the art to modify the method of reconstructing an organisms metabolism of Nakao et al. with the drug target identification of Karp et al. because shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 3 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 11/499,437. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Although the preambles between the claim 3 of the instant application and claim 1 of Application No. 11/499, 437 differ, the scope of the claims is in fact the same. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 are directed to the same use, namely to identify drug targets. Claim 1 of Application no. 11/499,437 is alternatively directed to identifying gene therapy targets. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 perform the same

steps, produce the same result, and recite identical claim language in the body of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 November 2007

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